

NKR 47, PICO 6: Individualiseret ernæringsindsats vs standardiseret ernæringsindsats

Review information

Authors

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Characteristics of studies

Characteristics of included studies

Persson 2007

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>Intervention</p> <ul style="list-style-type: none">● Age (Mean, SD): 85, 5.9● Sex(% male): Not reported● Co-morbidity (Yes/No): Not reported● Undernourished or at risk (Yes/No): Yes● Frail (Yes/No): Not reported● Impairment (Body functions and structure descriptions): Not reported● Limitations (Activity descriptions): Katz ADL index B (A-D)● Restrictions (participation description): Not reported● Housing (eg., residential homes, own house): Not reported● Civil status (% living alone): Not reported● In risk of falling (Yes/No): Not reported <p>Control</p> <ul style="list-style-type: none">● Age (Mean, SD): 85, 6.1● Sex(% male): Not reported● Co-morbidity (Yes/No): Not reported● Undernourished or at risk (Yes/No): Yes

	<ul style="list-style-type: none"> ● <i>Frail (Yes/No)</i>: Not reported ● <i>Impairment (Body functions and structure descriptions)</i>: Not reported ● <i>Limitations (Activity descriptions)</i>: Katz ADL index B (A-C) ● <i>Restrictions (participation description)</i>: Not reported ● <i>Housing (eg., residential homes, own house)</i>: Not reported ● <i>Civil status (% living alone)</i>: Not reported ● <i>In risk of falling (Yes/No)</i>: Not reported <p>Included criteria: Patients admitted to two wards at the Department of Geriatric Medicine at Rosenlund Hospital, Stockholm, were considered for participation in the study. Only patients with risk of PEM (defined as a total MNA score of <10 points) were asked to participate in the study.</p> <p>Excluded criteria: Patients with malignant disorders, terminal illness or with severe cognitive dysfunction were excluded</p> <p>Pretreatment: No significant differences at baseline on age, gender, living situation, MNA-SF, weight, BMI, grip strength, PEF, ADL, MMSE and QoL</p>
Interventions	<p>Intervention Characteristics</p> <p>Intervention</p> <ul style="list-style-type: none"> ● <i>Description</i>: The open intervention consisted of two individualized counseling sessions by a dietitian—once before discharge and then at home within 1 week of discharge. The dietitian also had telephone contact at three time points: 1-2 weeks after discharge, once in the middle of the study period and one week before follow-up. The patients were advised to increase their intake of fat by using full-fat milk instead of low-fat milk, cream and creme fraiche in their cooking and to eat more snacks between meals. They were also prescribed a liquid supplement (Sempers, 200 ml/package). Patients could choose between a complete or an incomplete formula corresponding to 85 or 120 kcal, respectively, and 4 or 5 g protein/100 ml. The patients were encouraged to take 1-2 packages/day and they were also prescribed a daily multivitamin supplement. Compliance with the prescription, i.e. how many of the prescribed packages that had been consumed, was recorded at all five contacts with the dietitian. ● <i>Duration (Weeks)</i>: 16 ● <i>Dose (eg. sessions, ml, energy/protein target)</i>: 2 x Individualized counselling sessions by a dietitian + 3 x telephone contacts + 1-2 liquid supplement/ day (85-100 kcal and 0-4 g protein) + multivitamin tablet. ● <i>Personel (eg. dietitian, nurse)</i>: Dietician <p>Control</p> <ul style="list-style-type: none"> ● <i>Description</i>: The control group was given brief written dietary advice. ● <i>Duration (Weeks)</i>: 16 ● <i>Dose (eg. sessions, ml, energy/protein target)</i>: None ● <i>Personel (eg. dietitian, nurse)</i>: Not relevant, as they are given written advice
Outcomes	<p><i>Kropsvægt (Body Weight) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Direction: Higher is better ● Data value: Endpoint <p><i>Kropsvægt (Body Weight) FU >6mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome

	<ul style="list-style-type: none"> ● Reporting: Not reported
<i>Muskelstyrke (Muscle Strength) FU <6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
<i>Mobilitet (Mobility) FU 3-6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
<i>Mobilitet (Mobility) FU >6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
<i>Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
<i>Hverdagsaktiviteter (Activities of Daily Living) FU >6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
<i>Livskvalitet (Quality of Life) FU 3-6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
<i>Livskvalitet, fysisk (Quality of Life, physical) FU 3-6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Fully reported ● Scale: SF-36 ● Unit of measure: points ● Direction: Higher is better ● Data value: Endpoint
<i>Livskvalitet, mental (Quality of life, mental) FU 3-6 mdr</i>	<ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
<i>Kvalme (nausea)</i>	<ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported
<i>Diaré (Diarrhea)</i>	<ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome

	<ul style="list-style-type: none"> ● Reporting: Not reported <p><i>Opkast (Vomit)</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported <p><i>Flatulens (Flatulence)</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported <p><i>Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Direction: Higher is better ● Data value: : Endpoint <p><i>Hverdagsaktiviteter (Activities of daily living) FU >6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported <p><i>Muskelstyrke (Muscle strength) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Fully reported ● Scale: Hand Grip Strength ● Unit of measure: kg ● Direction: Higher is better ● Data value: : Endpoint
Identification	<p>Sponsorship source: The study was carried out with the financial support from The Swedish Research Council (04224), Karolinska Institutet and by grants from S. Persson Family Foundation (18:35) and Semper Foods AB</p> <p>Country: Sweden</p> <p>Setting: Department of Geriatric Medicine at Rosenlund Hospital, Stockholm</p> <p>Comments: Patients are recruited at the hospital (the Department of Geriatric Medicine at Rosenlund Hospital, Stockholm). The intervention was initiated at the hospital at continued after discharge.</p> <p>Authors name: Margareta Persson</p> <p>Institution: Department of Geriatric Medicine, Dalens Hospital and Karolinska Institutet, Stockholm, Sweden</p> <p>Email: margareta.persson@sl.se</p> <p>Address: Department of Public Health and Caring Sciences, Clinical Nutrition and Metabolism Unit, Uppsala University, Uppsala, Sweden.</p>
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	Judgement Comment: No information given on the generation of sequence
Allocation concealment	Low risk	Judgement Comment: Randomization numbers were drawn from a sealed box (see annotation)
Blinding of participants and personnel	High risk	Judgement Comment: No blinding of participants and personnel: " The open intervention..." See annotation.
Blinding of outcome assessors	Unclear risk	Judgement Comment: There is no information about blinding of outcome assessors...
Incomplete outcome data	Low risk	Judgement Comment: There is a detailed description of patient flow during the study. Reason for drop-out is stated.
Selective outcome reporting	Unclear risk	Judgement Comment: All listed outcomes in their methods are reported in the result section. However, quality of life is only reported on patients treated-as-protocol and not in their ITT analysis. There is no reporting of a study protocol.
Other sources of bias	Low risk	

Rydwik 2008

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>Intervention</p> <ul style="list-style-type: none">● Age (Mean, SD): 83.1, 4.5● Sex(% male): 40● Co-morbidity (Yes/No): Not reported● Undernourished or at risk (Yes/No): Yes● Frail (Yes/No): Not clearly stated● Impairment (Body functions and structure descriptions): Not Reported● Limitations (Activity descriptions): 44% used outdoor walking aid at baseline● Restrictions (participation description): Not Reported● Housing (eg., residential homes, own house): Not Reported● Civil status (% living alone): Not Reported● In risk of falling (Yes/No): Mean One leg stance = 3.1 sec (median 1.7-5.9) <p>Control</p> <ul style="list-style-type: none">● Age (Mean, SD): 82.9, 4● Sex(% male): 30.4● Co-morbidity (Yes/No): Not Reported● Undernourished or at risk (Yes/No): Yes

	<ul style="list-style-type: none"> ● <i>Frail (Yes/No)</i>: Not clearly stated ● <i>Impairment (Body functions and structure descriptions)</i>: Not Reported ● <i>Limitations (Activity descriptions)</i>: 52% used outdoor walking aid at baseline ● <i>Restrictions (participation description)</i>: Not Reported ● <i>Housing (eg., residential homes, own house)</i>: Not Reported ● <i>Civil status (% living alone)</i>: Not Reported ● <i>In risk of falling (Yes/No)</i>: Mean One leg stance = 3.1 (median 2.3-6.8) <p>Included criteria: Community dwelling elderly, Age >75 years anda) unintentional weight loss $\geq 5\%$ and/or body mass index (BMI) ≤ 20 kg/m²; and b) low physical activity level (\leq grade 3 on a six-graded scale of physical activity)</p> <p>Excluded criteria: Exclusion criteria were age under 75, BMI >30kg/m², non-walkers, people with recent cardiac problems requiring hospital care, recent hip fracture or surgery during the last six months, present cancer treatment, stroke within the last two years, less than 7 points of a total 9-point score on the short form of the Mini Mental State Examination and institutionalization.</p> <p>Pretreatment:</p>
Interventions	<p>Intervention Characteristics</p> <p>Intervention</p> <ul style="list-style-type: none"> ● <i>Description</i>: Nutritional treatment consisted of individual dietary counseling, which was based on baseline food record data. Using the results of the food record, the dietitian/nutritionist tested different options that would cover the estimated needs of each individual, and then gave advice on food intake at an individual session lasting about one hour. Nutritional treatment included five group sessions covering such topics as the nutritional needs of elderly people, meal frequency and cooking methods. ● <i>Duration (Weeks)</i>: 12 ● <i>Dose (eg. sessions, ml, energy/protein target)</i>: 1 hour individual dietary counseling + 5 group sessions with different topics ● <i>Personel (eg. dietician, nurse)</i>: Dietician / nutritionist <p>Control</p> <ul style="list-style-type: none"> ● <i>Description</i>: General physical training advice and general diet advice. The general diet advice was to eat three main courses and 2-3 between-meal snacks including meat, fish or egg, fruit and vegetables, diary products and fiber, in combination with fluid. ● <i>Duration (Weeks)</i>: 12 ● <i>Dose (eg. sessions, ml, energy/protein target)</i>: Not relevant ● <i>Personel (eg. dietician, nurse)</i>: Not relevant
Outcomes	<p><i>Kropsvægt (Body Weight) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Fully reported ● Scale: vægt ● Unit of measure: kg ● Direction: Higher is better ● Data value: Change from baseline <p><i>Kropsvægt (Body Weight) FU >6mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome

- **Reporting:** Fully reported
- **Scale:** vægt
- **Unit of measure:** kg
- **Direction:** Higher is better
- **Data value:** Change from baseline

Muskelstyrke (Muscle Strength) FU <6mdr

- **Outcome type:** ContinuousOutcome
- **Reporting:** Fully reported
- **Scale:** Leg press
- **Unit of measure:** kilogram
- **Direction:** Higher is better
- **Data value:** Change from baseline

Mobilitet (Mobility) FU 3-6 mdr

- **Outcome type:** ContinuousOutcome
- **Reporting:** Fully reported
- **Scale:** Maximal walking speed
- **Unit of measure:** Meter/sekund
- **Direction:** Higher is better
- **Data value:** Change from baseline

Mobilitet (Mobility) FU >6 mdr

- **Outcome type:** ContinuousOutcome
- **Reporting:** Fully reported
- **Scale:** Maximal walking speed
- **Unit of measure:** Meter/ sekund
- **Direction:** Higher is better
- **Data value:** Change from baseline

Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr

- **Outcome type:** ContinuousOutcome
- **Reporting:** Not reported
- **Notes:** Measured but results are not reported

Hverdagsaktiviteter (Activities of Daily Living) FU >6 mdr

- **Outcome type:** ContinuousOutcome
- **Reporting:** Not reported
- **Notes:** Measured but not reported

Livskvalitet (Quality of Life) FU 3-6 mdr

- **Outcome type:** ContinuousOutcome

	<ul style="list-style-type: none">● Reporting: Not reported <p><i>Livskvalitet, fysisk (Quality of Life, physical) FU 3-6 mdr</i></p> <ul style="list-style-type: none">● Outcome type: ContinuousOutcome● Reporting: Not reported <p><i>Livskvalitet, mental (Quality of life, mental) FU 3-6 mdr</i></p> <ul style="list-style-type: none">● Outcome type: ContinuousOutcome● Reporting: Not reported <p><i>Kvalme (nausea)</i></p> <ul style="list-style-type: none">● Outcome type: DichotomousOutcome● Reporting: Not reported <p><i>Diaré (Diarrhea)</i></p> <ul style="list-style-type: none">● Outcome type: DichotomousOutcome● Reporting: Not reported <p><i>Opkast (Vomit)</i></p> <ul style="list-style-type: none">● Outcome type: DichotomousOutcome● Reporting: Not reported <p><i>Flatulens (Flatulence)</i></p> <ul style="list-style-type: none">● Outcome type: DichotomousOutcome● Reporting: Not reported <p><i>Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr</i></p> <ul style="list-style-type: none">● Outcome type: DichotomousOutcome● Reporting: Not reported <p><i>Hverdagsaktiviteter (Activities of daily living) FU >6 mdr</i></p> <ul style="list-style-type: none">● Outcome type: DichotomousOutcome● Reporting: Not reported <p><i>Muskelstyrke (Muscle Strength) FU 3-6 mdr</i></p> <ul style="list-style-type: none">● Outcome type: ContinuousOutcome● Reporting: Fully reported● Scale: Leg press● Unit of measure: Kilogram● Direction: Higher is better● Data value: Change from baseline
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Identification	<p>Sponsorship source: Not reported</p> <p>Country: Sweden</p> <p>Setting: Municipality of Solna</p> <p>Comments: No details on sponsorship sources</p> <p>Authors name: Elisabeth Rydwick</p> <p>Institution: Research and Development Unit for the Elderly North, Jakobsbergs Hospital, Karolinska Institute</p> <p>Email: elisabeth.rydwick@sl.se</p> <p>Address: Research and Development Unit for the Elderly, North, Jakobsbergs Hospital, Karolinska Institutet, Järfälla</p>
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	Judgement Comment: No information on how the allocation sequence was generated
Allocation concealment	High risk	Judgement Comment: "The randomization procedure was conducted in an open manner by the study personnel, instructed by a statistician". - Hence, allocation was not concealed.
Blinding of participants and personnel	Unclear risk	Judgement Comment: Personnel were not blinded - "The randomization procedure was conducted in an open manner by the study personnel, instructed by a statistician". It is, however, not stated if participants were blinded. With these interventions I find blinding of participants very unlikely...
Blinding of outcome assessors	Unclear risk	Judgement Comment: The authors do not report any blinding of the outcome assessors. Assessment of outcome is performed by the personnel responsible for interventions.
Incomplete outcome data	High risk	Judgement Comment: Exclusion from the study is described in fig. 1. In the Intervention Group 3 participants are lost to follow-up at the 1st FU (rejected = 2, Deceased=1) and 4 participants are lost to follow-up at the 2nd FU (Too tired=2, Rejected=1, Hospital=1). In the Control Group 4 participants are lost to follow-up at the 1st FU (Too tired=1, Rejected=2, Hospital=1) and 6 are lost to follow-up at the 2nd FU (Too tired=5, Deceased=1). Reasons are given for each participant, but it is a concern that there is a high drop-out rate and that the weakest participants are lost. "Between group analyses were conducted with an intention-to-treat analysis, including all subjects regardless of compliance..."
Selective outcome reporting	Unclear risk	Judgement Comment: Results on IADL are not reported. They are, however, including in the analysis of improvers vs. non-improvers. Results on IADL are not reported. They are, however, including in the analysis of improvers vs. non-improvers.
Other sources of bias	Low risk	Judgement Comment: A small baseline difference in gender distribution, which might favor the control group.

Schilp 2014

Methods	<p>RCT by Janneke Schilp</p> <p>A parallel randomized controlled trial was performed in 146 non-institutionalized, undernourished individuals aged 65 years in primary care. Participants were randomly assigned to the intervention (referral to and treatment by a trained dietitian) or control group (no referral). Body weight, physical performance, handgrip strength, energy intake, protein intake and fat-free mass were assessed at baseline, after 3 months and after 6 months.</p>
Participants	<p>Inclusion:</p> <p>Individuals were eligible for NPCS if they were non-institutionalized and were identified as undernourished according to the Short Nutritional Assessment Questionnaire 65? (SNAQ65?). The SNAQ65? was recently developed and validated to determine undernutrition fast and feasible specifically in community-dwelling older individuals [22]. Other screening instruments including the assessment of body weight, which is an impractical measure for the home situation, are less specific for assessing undernutrition. Undernutrition was defined as a mid-upper arm circumference (MUAC) ≥ 25 cm and/or self report of ≥ 4 kg unintentional weight loss within the past 6 months. MUAC was measured with a measuring tape at the center point of the left upper arm to the nearest mm with the arm hanging loosely. Unintentional weight loss was assessed by the question: "Have you unintentionally lost 4 kg or more within the past 6 months?"</p> <p>Exclusion:</p> <p>Individuals were excluded from enrollment if they were under current dietetic treatment, were medically diagnosed with dementia, were not living in vicinity of Amsterdam (where the treatment is provided) or were not speaking the Dutch language. Severely overweight (MUAC ≥ 32 cm) individuals were also excluded from the study as it is unclear whether weight gain would be advisable for these individuals [23]. A MUAC ≥ 32 cm corresponds with a BMI ≥ 28 kg/m², based on data from 2,141 individuals aged 65 years (data available by request from authors).</p>
Interventions	<p>Participants of the intervention group received dietetic treatment from a qualified trained dietitian.</p> <p>The control group received usual care and was not referred to a dietitian through the study. They received a standard brochure of the Netherlands Nutrition Centre with general information about healthy eating habits.</p>
Outcomes	<p>Primary outcome:</p> <p>measures Body weight was measured without shoes to the nearest 0.5 kg using a calibrated mechanical scale (Seca 761). Adjustments were made for clothing (-1.77 kg for men; -1.13 kg for women), and in deviating situations, adjustments were made for shoes (-0.40 kg for men; -0.28 kg for women) or corset (-1 kg) (respectively, 3 and 1 % of all assessments) [30, 31]. Physical performance was assessed using the Short Physical Performance Battery which consists of a 4-m walk test, repeated chair stands test and standing balance test [32]. The total score ranged from 0 (worst performance) to 12. Handgrip strength (kg) was measured twice on each hand using a handheld dynamometer (JAMAR; Sammons Preston, UK). The mean value of the maxima of both hands was used. If the left or right handgrip strength measure was missing at an examination, this measure was also set to missing at the previous or follow-up examinations. Eur J Nutr (2013) 52:1939-1948 1941 123</p> <p>Secondary outcome:</p> <p>measures A food diary was filled in by the participant the day prior to each examination and was reviewed for completeness by the researcher (or assistant) during the examination. If missing, a 24-hour recall was conducted during the examination. Daily energy (kcal) and protein (gram) intake were calculated using the NEVO Dutch Food Composition Table 2006 [33]. A copy of the baseline examination food diary and the calculation of the baseline energy and protein intake were sent to the treating dietitian. Whole-body resistance (R, Ohm) was measured at the left side of the body at a frequency of 50 kHz using a Bodystat 1500 MDD (Euromedix, Belgium). Fat-free mass (kg) was predicted with the formula of Kyle (2001) [34]. Participants with an invalid measurement (fat percentage ≥ 5 %) were excluded from the analysis (7.5 %) [35]. Other</p>

	reasons for missing data were as follows: shoes could not be taken off (1.3 %), dysfunction of the equipment (2.0 %), pacemaker (3.0 %), presence of stocking or bandages (3.8 %) and not able/refuse (5.3 %).
Identification	J. Schilp (&) H. M. Kruijenga H. A. H. Wijnhoven M. Visser (&) Department of Health Sciences and the EMGO Institute for Health and Care Research, VU University Amsterdam, De Boelelaan 1085, 1081 HV Amsterdam, The Netherlands e-mail: janneschilp@hotmail.com 14 June 2012 / Accepted: 14 January 2013 / Published online: 30 January 2013 Springer-Verlag Berlin Heidelberg 2013
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Random allocation to either the intervention group or the control group was individually performed in blocks of 4 and 6 by using the website randomization.com (http://www.randomization.com)
Allocation concealment	Unclear risk	They do not state if the allocation was concealed. The randomization was performed by the primary investigator within 1 day after completion of the baseline examination. Random allocation to either the intervention group or the control group was individually performed in blocks of 4 and 6 by using the website randomization.com (http://www.randomization.com). Participants recruited at an outpatient clinic department were randomized with a separate scheme, because they were expected to be more severely undernourished.
Blinding of participants and personnel	High risk	Participants, researcher and research assistants were no longer blinded for the intervention assignment from this point (after randomization).
Blinding of outcome assessors	High risk	Participants, researcher and research assistants were no longer blinded for the intervention assignment from this point (after randomization).
Incomplete outcome data	Low risk	The study was registered at the Dutch Trial Register (http://www.trialregister.nl) NTR1808. They report all the outcomes they measure. Therefore I judge the risk of incomplete outcome data low.
Selective outcome reporting	Low risk	The study was registered at the Dutch Trial Register (http://www.trialregister.nl) NTR1808.
Other sources of bias	Low risk	None detected

Stow 2015

Methods	Study design: Cluster randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT: YES
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Participants	Intervention
	<p>Baseline Characteristics</p> <ul style="list-style-type: none"> ● Age (Mean, SD): Not reported ● Sex(% male): 18.8 ● Co-morbidity (Yes/No): Not reported ● Undernourished or at risk (Yes/No): Yes ● Frail (Yes/No): Not reported ● Impairment (Body functions and structure descriptions): Not reported ● Limitations (Activity descriptions): Not reported ● Restrictions (participation description): Not reported ● Housing (eg., residential homes, own house): residential and/or nursing homes ● Civil status (% living alone): Not reported ● In risk of falling (Yes/No): Not reported <p>Control</p> <ul style="list-style-type: none"> ● Age (Mean, SD): Not reported ● Sex(% male): 20.7 ● Co-morbidity (Yes/No): Not reported ● Undernourished or at risk (Yes/No): Yes ● Frail (Yes/No): Not reported ● Impairment (Body functions and structure descriptions): Not reported ● Limitations (Activity descriptions): Not reported ● Restrictions (participation description): Not reported ● Housing (eg., residential homes, own house): residential and/or nursing homes ● Civil status (% living alone): Not reported ● In risk of falling (Yes/No): Not reported <p>Included criteria: Inclusion criteria for residents were as follows: 1. A score of '1' or higher on the 'Malnutrition Universal Screening Tool', 2. Able to eat and drink, and 3. Registered with a Solihull General Practitioner and subsequently eligible for the provision of healthcare services provided by the Heart of England NHS foundation Trust.</p> <p>Excluded criteria: Exclusion criteria for residents were as follows: 1. Receiving (or likely to receive in the next 6 months) enteral tube feeding or parenteral nutrition; 2. Receiving nutritional support in the form of dietetic advice or prescribed ONS; 3. Have a known eating disorder or illness, which requires a therapeutic diet incompatible with fortification and/or supplementation; or 4. On an end-of-life care pathway. Exclusion criteria for Participant Reported Outcome Measures (PROMs) include the following: 1. Non-native English speaking or 2. Lacking the capacity to consent</p> <p>Pretreatment: There was a noted difference in the proportion of residents at medium and high risk of malnutrition in the care home assigned to the FB intervention (34 % high risk compared to >60 % for the other two arms). The mean values for weight (kg), energy intake (kcal) and fluid intake (ml) were also higher for the FB residents than the residents in the care homes allocated to ONS.</p>

<p>Interventions</p>	<p>Intervention Characteristics Intervention</p> <ul style="list-style-type: none"> ● <i>Description:</i> Care staff and catering teams in the two homes randomised to intervention, received face-to-face instruction from the Primary Researcher to increase the participating resident's daily nutritional intake by approximately 600 kcal and 20 to 25 g of protein. The choices of supplement drinks and snacks presented were discussed in relation to the preferences of the resident and the resources and time available at the home. The agreed intervention combination was documented for each resident, at baseline and at 3 months, and recipes were provided. ● <i>Duration (Weeks):</i> 24 ● <i>Dose (eg. sessions, ml, energy/protein target):</i> The intervention targeted an increase in the participating resi-dent's daily nutritional intake by approximately 600 kcal and 20 to 25 g of protein. ● <i>Personel (eg. dietician, nurse):</i> Care staff and catering team instructed by dietitian <p>Control</p> <ul style="list-style-type: none"> ● <i>Description:</i> Nursing and/or senior care staff in the two homes allocated to the ONS intervention received instruction by the Primary Researcher to increase the daily nutritional intake of participating residents by approximately 600 kcal and 24 g protein. In accordance with local nutrition support guidelines, the intervention consisted of two liquid ONS , provided to residents under the control of a registered dietitian. Staff were asked to record the time of the intervention provision and resident intake on the daily drugs chart as a proportion taken ● <i>Duration (Weeks):</i> 24 ● <i>Dose (eg. sessions, ml, energy/protein target):</i> The intervention targeted an increase in the participating resi-dent's daily nutritional intake by approximately 600 kcal and 24 g of protein ● <i>Personel (eg. dietician, nurse):</i> Care staff instructed by dietitian
<p>Outcomes</p>	<p><i>Kropsvægt (Body Weight) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Fully reported ● Scale: vægt ● Unit of measure: kg ● Direction: Higher is better ● Data value: Change from baseline <p><i>Kropsvægt (Body Weight) FU >6mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported <p><i>Muskelstyrke (Muscle Strength) FU <6mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported <p><i>Mobilitet (Mobility) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported

	<p><i>Mobilitet (Mobility) FU >6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
	<p><i>Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
	<p><i>Hverdagsaktiviteter (Activities of Daily Living) FU >6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome
	<p><i>Livskvalitet (Quality of Life) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
	<p><i>Livskvalitet, fysisk (Quality of Life, physical) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
	<p><i>Livskvalitet, mental (Quality of life, mental) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Not reported
	<p><i>Kvalme (nausea)</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported
	<p><i>Diaré (Diarrhea)</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported
	<p><i>Opkast (Vomit)</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported
	<p><i>Flatulens (Flatulence)</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported
	<p><i>Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome ● Reporting: Not reported
	<p><i>Hverdagsaktiviteter (Activities of daily living) FU >6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: DichotomousOutcome

	<ul style="list-style-type: none"> ● Reporting: Not reported <p><i>Muskelstyrke (muscle strength) FU 3-6 mdr</i></p> <ul style="list-style-type: none"> ● Outcome type: ContinuousOutcome ● Reporting: Fully reported ● Scale: Hand Grip Strength ● Unit of measure: kg ● Direction: Higher is better ● Data value: Change from baseline
Identification	<p>Sponsorship source: This trial was undertaken as a student project, as part of the National Institute for Health Research (NIHR) Clinical Academic Training Programme for AHP's (Masters in Research). The study was self-funded and involved no research costs for the NHS trust sponsoring the research (The Heart of England NHS Foundation Trust). The trial sponsor had no involvement in the study design, in the collection, analysis and interpretation of the data; in the writing of the report; and in the decision to submit the paper for publication. Fortisip bottle and Fortisip compact are manufactured by Nutricia Advanced Medical Nutrition and were provided by Nutricia for use within the first 3 months of the trial. Nutriplen is manufactured by Nutralta Ltd and was provided by Nutralta for the second 3 months of the trial</p> <p>Country: England</p> <p>Setting: Residential homes, Nursing homes and Residential and Nursing homes within the borough of Solihull, West Midlands</p> <p>Comments:</p> <p>Authors name: Ruth Stow</p> <p>Institution: Health Research MRes, University of Birmingham, School of Sport, Exercise and Rehabilitation Sciences</p> <p>Email: ruth.stow@nottingham.ac.uk</p> <p>Address: Room 30, North Laboratory Building, Sutton Bonington Campus, Leicestershire LE12 5RD, UK.</p>
Notes	<p>Nkr 47 Geria on 06/04/2016 23:22</p> <p>Interventions</p> <p>The study has three arms. One with a food based intervention (Here named the Intervention Group), one group with a ONS intervention (Here named the Control Group) and one group receiving standard care (Not included in this data extraction)</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Quote: "The random allocation sequence was generated using a computer-generated random number list at the University of Birmingham Clinical Trials Unit."
Allocation concealment	Low risk	Judgement Comment: Allocation concealment is detailed described in the article, see annotation.
Blinding of participants and personnel	Low risk	Judgement Comment: Participants were blinded to the care home intervention assignment. However, personnel at the care homes were not blinded. The risk is considered low, as the personnel were not responsible for the assessment of outcomes. See annotation.

Blinding of outcome assessors	Low risk	Quote: "This trial had one Primary Researcher, responsible for communicating intervention allocation to participating homes and conducting outcome assessments. It was therefore impossible to blind the primary researcher to the assigned intervention. To minimise bias, the chosen outcome measures were objective and not easily influenced by the observer." Judgement Comment: As the results from this trial includes only weight and hand grip strength I judge that the risk of bias is low, as these are objective measures.
Incomplete outcome data	High risk	Quote: "Of the 32 residents in the care homes assigned to SC, two moved out, and 11 died within 6 months. Of the 32 residents in the care homes assigned to FB intervention, two entered end-of-life care, one moved out, and six died. Of the 29 residents in the care homes assigned to ONS intervention, one moved out, one was admitted to the hospital and six died. A total of 63 residents completed the trial by the end of June 2014 and were included in the analyses." Judgement Comment: I judge the risk of bias high, as the weakest participants (admitted or died) are those who no data is available on, why results are likely to be affected by this. However, the death rate seems to be equally distributed between the groups.
Selective outcome reporting	Low risk	Quote: "The trial was registered at www.isrctn.com (Current Controlled Trials ISRCTN38047922)." Judgement Comment: The trial was registered at ISRCTN (see annotation). The only results that are not reported in the article is on PROMS (e.g. Quality of life), due to the very low number of participants.
Other sources of bias	Low risk	Quote: "There was a noted difference in the proportion of residents at medium and high risk of malnutrition in the care home assigned to the FB intervention (34 % high risk compared to >60 % for the other two arms). The mean values for weight (kg), energy intake (kcal) and fluid intake (ml) were also higher for the FB residents than the residents in the care homes allocated to SC and ONS." Judgement Comment: I judge low risk of bias because there is baseline imbalances between groups, but they are moderate rather than extreme

Footnotes

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Data and analyses

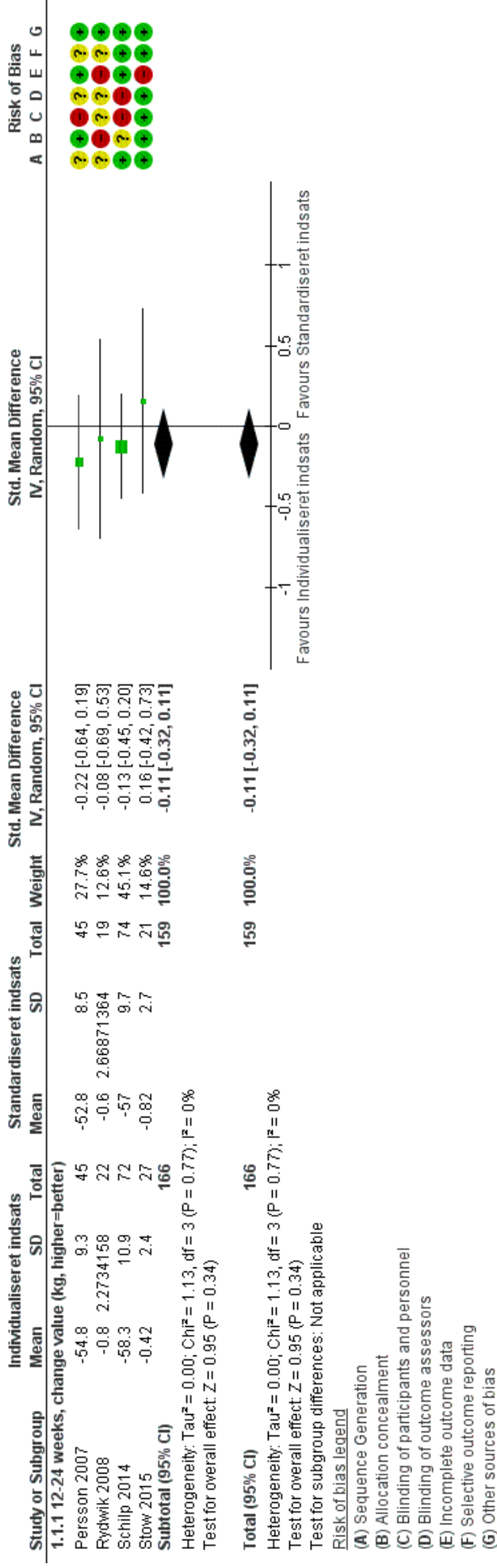
1 Individualiseret indsats vs Standardiseret indsats

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Kropsvægt (Body Weight) FU 3-6 mdr (EOT)	4	325	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.32, 0.11]
1.1.1 12-24 weeks, change value (kg, higher=better)	4	325	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.32, 0.11]
1.2 Kropsvægt (Body Weight) FU >6mdr (FU)	2	76	Mean Difference (IV, Random, 95% CI)	-0.61 [-2.16, 0.95]
1.2.1 4-6 months, kg, higher=better	2	76	Mean Difference (IV, Random, 95% CI)	-0.61 [-2.16, 0.95]
1.3 Mobilitet (Mobility) FU 3-6 mdr	2	187	Std. Mean Difference (IV, Random, 95% CI)	-0.06 [-0.35, 0.22]
1.3.1 12-26 weeks	2	187	Std. Mean Difference (IV, Random, 95% CI)	-0.06 [-0.35, 0.22]
1.4 Mobilitet (Mobility) FU >6 mdr	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.5 Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr	1	41	Mean Difference (IV, Fixed, 95% CI)	1.00 [-0.67, 2.67]
1.5.1 FIM (0-91)	1	41	Mean Difference (IV, Fixed, 95% CI)	1.00 [-0.67, 2.67]
1.6 Hverdagsaktiviteter (Activities of Daily Living) FU >6 mdr	1	34	Mean Difference (IV, Fixed, 95% CI)	-1.00 [-3.73, 1.73]
1.6.1 FIM (0-91)	1	34	Mean Difference (IV, Fixed, 95% CI)	-1.00 [-3.73, 1.73]
1.7 Livskvalitet (Quality of Life) FU 3-6 mdr	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

1.8 Livskvalitet, fysisk (Quality of Life, physical) FU 3-6 mdr	1		54	Mean Difference (IV, Fixed, 95% CI)	-14.00 [-78.43, 50.43]
1.8.1 SF-36 (higher=better), 16 weeks, final value	1		54	Mean Difference (IV, Fixed, 95% CI)	-14.00 [-78.43, 50.43]
1.9 Livskvalitet, mental (Quality of life, mental) FU 3-6 mdr	1		54	Mean Difference (IV, Fixed, 95% CI)	2.00 [-59.37, 63.37]
1.9.1 SF-36 (higher=better), 16 weeks, final value	1		54	Mean Difference (IV, Fixed, 95% CI)	2.00 [-59.37, 63.37]
1.10 Muskelstyrke (muscle strength) FU 3-6 mdr	4		300	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.36, 0.10]
1.10.1 12-24 weeks, higher=better (kg)	4		300	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.36, 0.10]
1.11 Muskelstyrke (Muscle Strength) FU <6mdr	2		49	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.69, 0.45]
1.11.1 4-6 months, Change values (kg), Higher=better	2		49	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.69, 0.45]
1.14 Kvalme (nausea)	0			Risk Ratio (IV, Fixed, 95% CI)	No totals
1.15 Diaré (Diarrhea)	0			Risk Ratio (IV, Fixed, 95% CI)	No totals
1.16 Opkast (Vomit)	0			Risk Ratio (IV, Fixed, 95% CI)	No totals
1.17 Flatulens (Flatulence)	0			Risk Ratio (IV, Fixed, 95% CI)	No totals
1.18 Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr	1		54	Risk Ratio (IV, Fixed, 95% CI)	0.92 [0.56, 1.51]
1.18.1 At 16 weeks, final value, Katz score (dichotomized), event=independent	1		54	Risk Ratio (IV, Fixed, 95% CI)	0.92 [0.56, 1.51]
1.19 Hverdagsaktiviteter (Activities of daily living) FU >6 mdr	0			Risk Ratio (IV, Fixed, 95% CI)	No totals

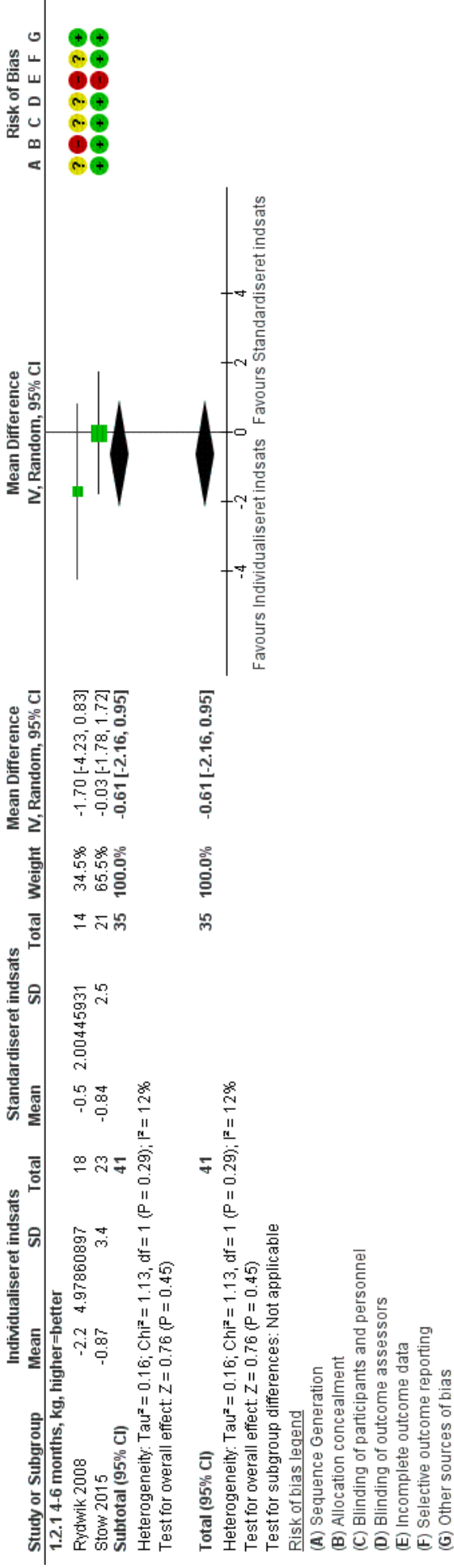
Figures

Figure 1 (Analysis 1.1)



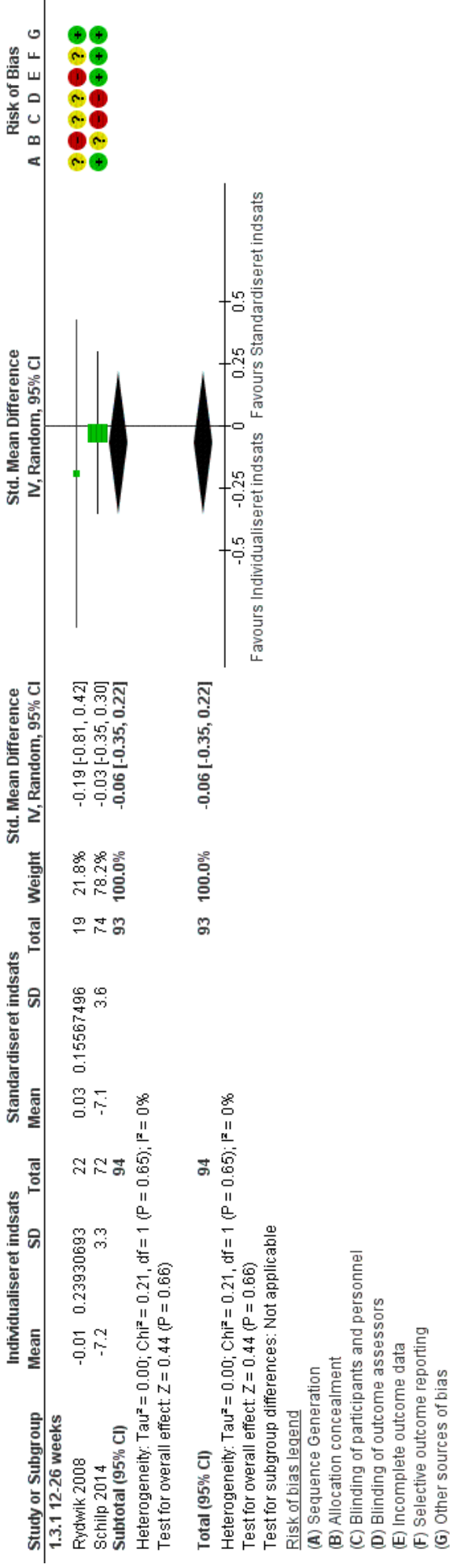
Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.1 Kropsvægt (Body Weight) FU 3-6 mdr (EOT).

Figure 2 (Analysis 1.2)



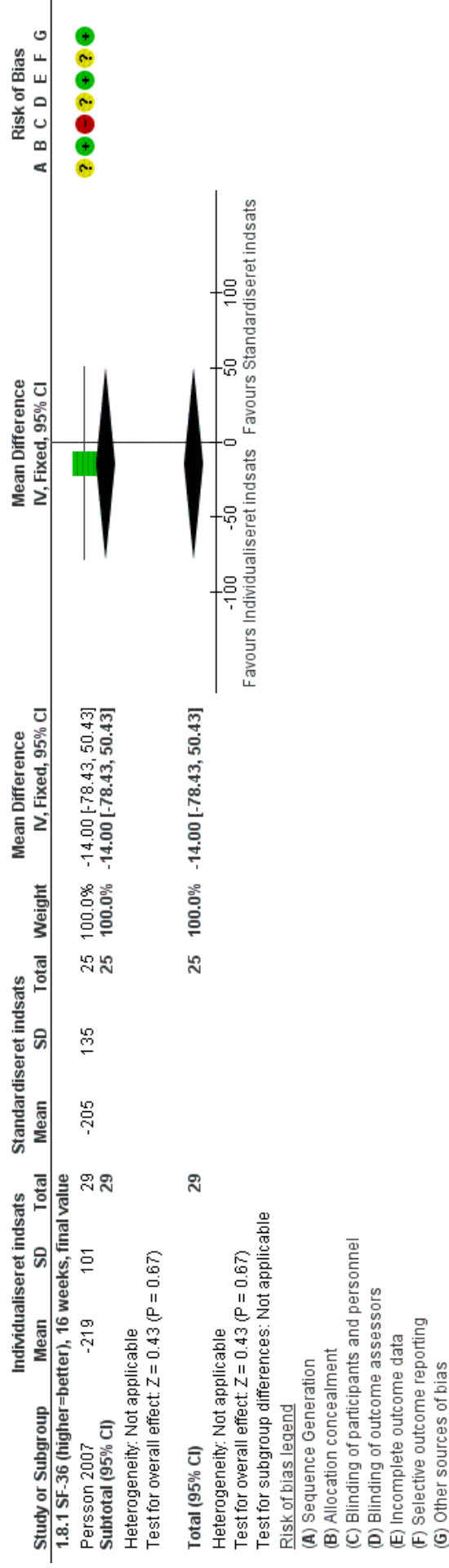
Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.2 Kropsvægt (Body Weight) FU >6mdr (FU).

Figure 3 (Analysis 1.3)



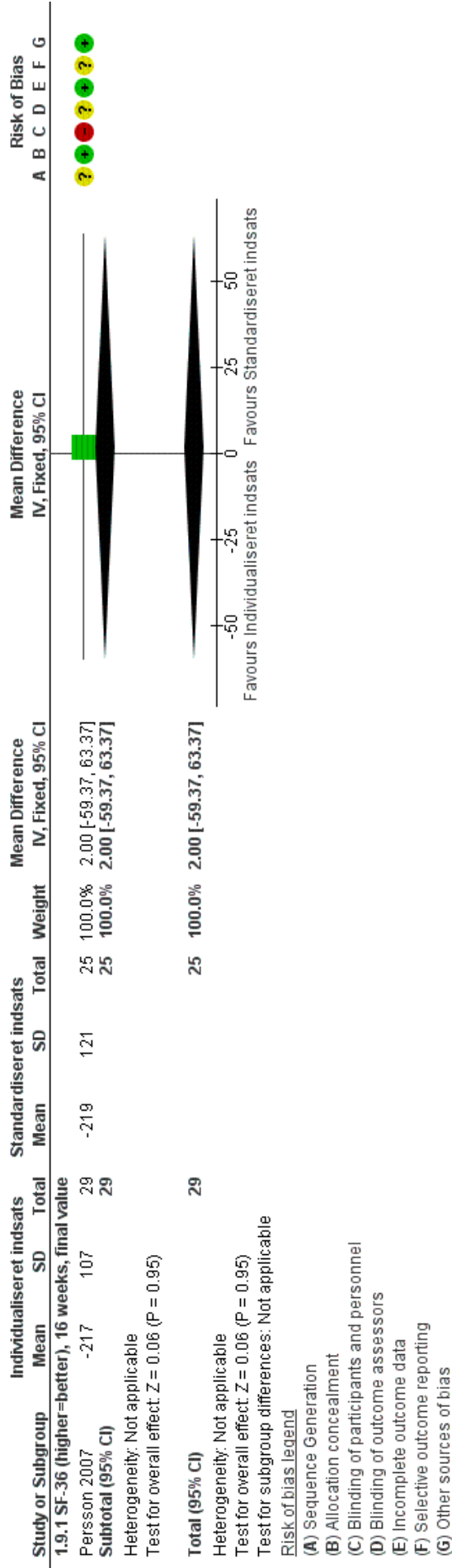
Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.3 Mobilitet (Mobility) FU 3-6 mdr.

Figure 4 (Analysis 1.8)



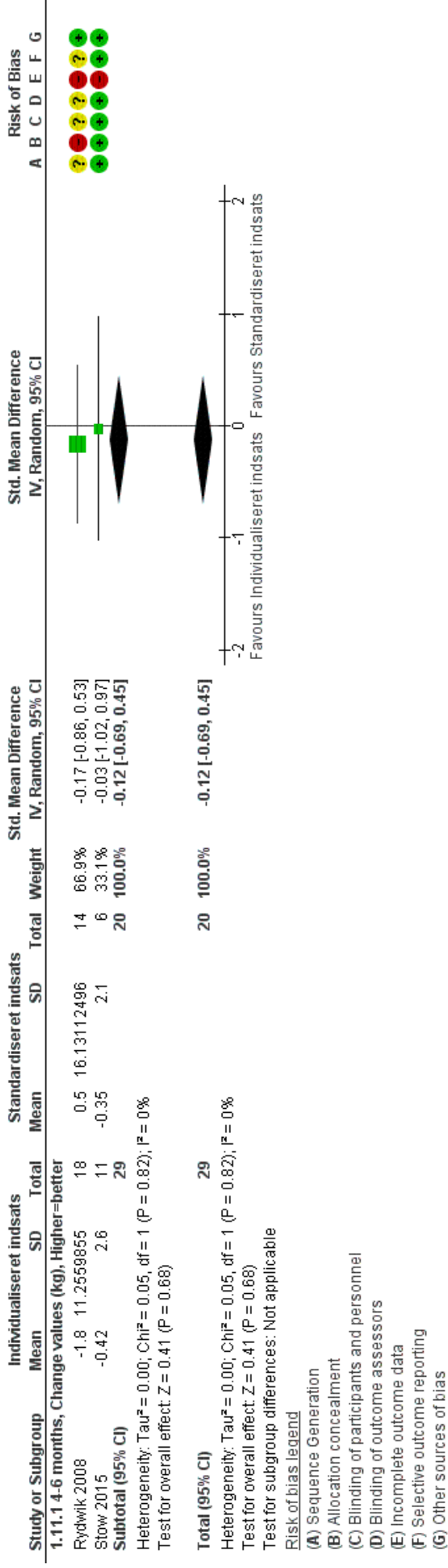
Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.8 Livskvalitet, fysisk (Quality of Life, physical) FU 3-6 mdr.

Figure 5 (Analysis 1.9)



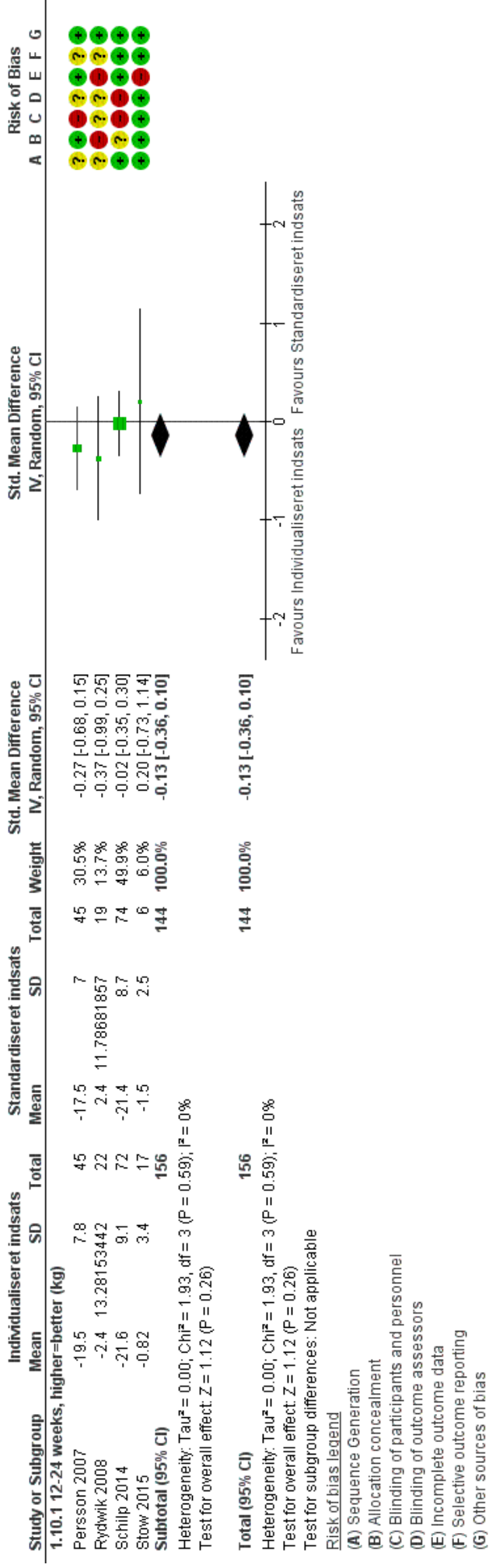
Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.9 Livskvalitet, mental (Quality of life, mental) FU 3-6 mdr.

Figure 6 (Analysis 1.11)



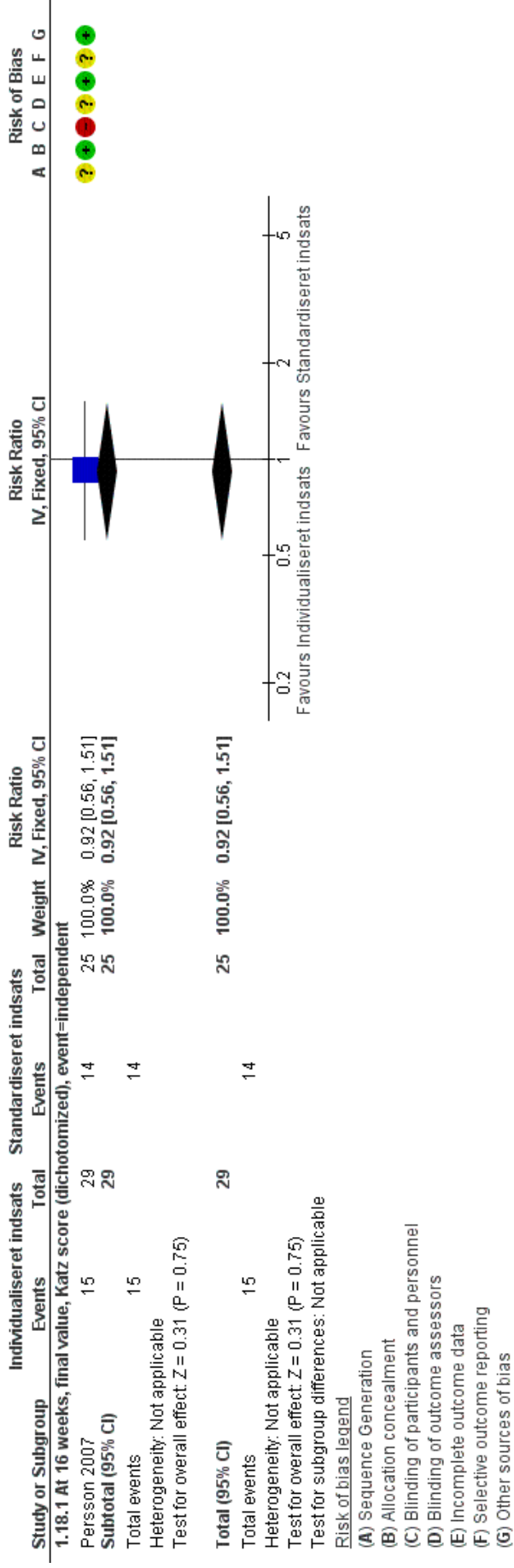
Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.11 Muskelstyrke (Muscle Strength) FU <6mdr.

Figure 7 (Analysis 1.10)



Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.10 Muskelstyrke (muscle strength) FU 3-6 mdr.

Figure 8 (Analysis 1.18)



Forest plot of comparison: 1 Individualiseret indsats vs Standardiseret indsats, outcome: 1.18 Hverdagsaktiviteter (Activities of daily living) FU 3-6 mdr.

Figure 9

	Sequence Generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessors	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Persson 2007	?	+	-	?	+	?	+
Rydwik 2008	?	-	?	?	-	?	+
Schilp 2014	+	?	-	-	+	+	+
Stow 2015	+	+	+	+	-	+	+

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.